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14. ABSTRACT
A hybrid neuromechanical ambulatory assist system is being developed for walking after lower extremity paralysis that combines the stability and constraints of a novel hydraulic exoskeletal system with the mobility powered by the individual's own paralyzed muscles contracting via functional electrical stimulation. A mobile computing platform is designed to provide real-time closed-loop control using brace mounted sensors to deliver the stimulation needed to stand up and walk while coordinating exoskeletal control mechanisms at the hips and knees to maintain stability. A variable constraint hip mechanism couples hips as needed to maintain posture and reduces the need for upper extremities to maintain balance. The knee locking mechanism is designed to allow the stimulated muscles to rest during stance while permitting unconstrained movement during swing. A knee flexion assist is being explored to provide sufficient foot clearance during swing on an uneven terrain. The exoskeleton is designed for easy fitting with adjustable uprights and hip abduction for donning for use in activities of daily living for persons with paraplegia.

15. SUBJECT TERMS
Exoskeleton, hydraulic, spinal cord injury, walking

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Table of Contents

Page

INTRODUCTION

The first prototype of the Hybrid Neuroprosthesis (HNP1) for walking in paraplegia was a combination of a controllable exoskeleton to provide stability, and functional neuromuscular stimulation (FNS) to power joint movements via contractions of the paralyzed muscles (Kobetic 2009). The HNP1 incorporated two mechanisms for control of knees and hips – the Dual State Knee Mechanism (DSKM) which locked the knee for stance and unlocked it for swing (To 2011), and the Variable Constraint Hip Mechanism (VCHM) which locked the hip for stance, unlocked it for swing or reciprocally coupled the two hips to maintain posture (To 2008). The HNP1 was controlled by an off-board lab computer that read in the sensor data, determined phases of gait, applied the knee and hip joint constraints and modulated stimulation using a state based controller (To 2012, 2014). In persons with paraplegia from SCI, the HNP1 significantly reduced the forward lean of FNS-only walking and the maximum upper extremity forces for balance and support by 42 % and 19%, respectively, as compared to the isocentric reciprocal gait orthosis (IRGO) and FNS-only gait. The speed of walking with the HNP1 was significantly faster than with the IRGO and comparable to FNS-only with less stimulation, thus potentially reducing muscle fatigue. Drawbacks of the HNP1 were weight of the exoskeleton, lack of adjustability for fitting different users, limited knee flexion in early swing to provide proper toe clearance and being tethered to the lab based computer, thus not conducive to clinical evaluation or out-of-laboratory use. The purpose of this research is to refine the design of the hybrid neuromechanical gait assist system and generate a prototype HNP2 which will address these drawbacks and prepare it for evaluation under real-world conditions outside of the laboratory environment.

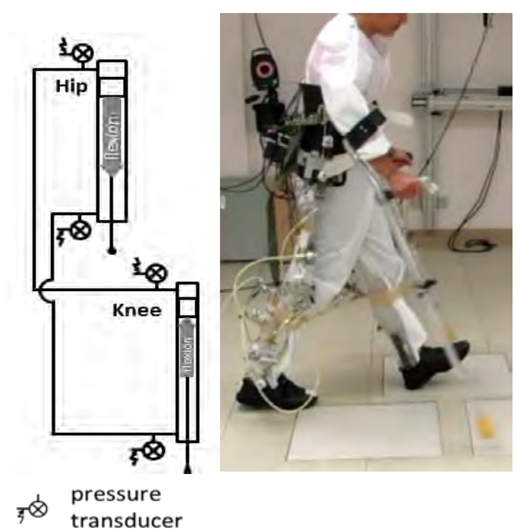
BODY

Work Accomplished under Current Aims

Task 1 – Design and implement new hydraulic hardware and control algorithms for synergistic coupling of hip and knee flexion during walking, including online adjustment of orthosis constraints and electrical stimulation.

HKC mechanism

A simple version of the hip-knee coupling (HKC) hydraulic mechanism (**Figure 1a**) with off-the-shelve components was incorporated into the HNP1 hardware to coordinate flexion of the hip and knee joints during swing phase of gait. The hip and knee hydraulic cylinders were the 7/8" and 9/16" bore cylinders, respectively, to achieve approximate HKC ratio of 1:2. The connections were between rod side of the hip cylinder and rod side of the knee cylinder (as well as blind side of the hip cylinder and blind side of the knee cylinder). The system was pressurized to



a) b)

Figure 1. a) HKC hydraulic circuit, **b**) able-bodied subject walking with HKC mechanism.

approximately 60 psi to minimize compliance due to entrapped air. The exoskeleton with bilateral HKC mechanism engaged was evaluated by an able bodied volunteer (**Figure 1b**) and a subject with paraplegia from SCI (**Figure 3**). Both consented to participate in evaluation under an approved Cleveland VA Medical Center IRB protocol for brace evaluation. VICON motion analysis system, pressure sensor and potentiometer data were collected and post-processed to determine hip-knee coupling ratios.

Able-bodied subject evaluation of HKC – The ratio between the hip and knee (**Figure 2**) during the first half of swing phase was 1°:0.71±0.02° and 1°:1.84±0.11° during the second half of swing. Approximately linear relationship was found between joint angle and the stroke length of the cylinder, however, there was no change in knee angle with significant change in hip angle during stance. The hip and knee joints showed some level of coupling as they both flexed (and extended) during swing phase. The inconsistent hip-knee coupling may have been due to poor mechanical coupling of exoskeletal joints (i.e. rack and pinion), compliance in the hydraulics due to entrapped air and compliance in body-brace coupling. As a result, the early swing phase HKC ratio was not favorable for its implementation. It is not clear whether the subject took advantage of system compliance and used compensatory strategies in order to clear the foot including side-to-side leaning, circumduction of the swinging leg, hip hiking or volitionally assisted knee flexion.

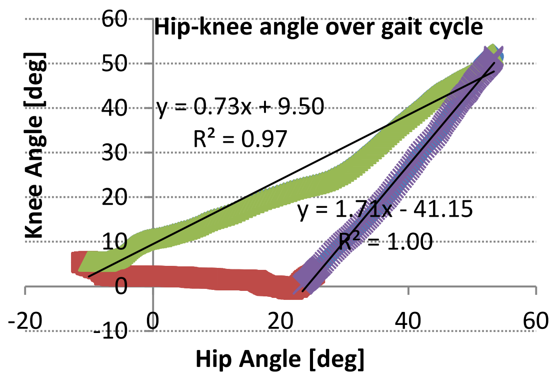


Figure 2. Linear fit to swing phase of hip-knee angle (first half of swing **-** green, second half**-** purple, and stance phase **–**red).

SCI subject evaluation of HKC –The subject initiated steps by pressing a finger switch to activate a pre-programmed pattern of stimulation delivered via percutaneous intramuscular electrodes to generate cyclic walking movements at a self selected speed while he had a standby assist for safety (**Figure 3**). Approximate hip-knee angle ratios were determined by linear fitting of the ensemble averages of hip-

Figure 3. Representative stride of hip-knee coupling condition, starting at left heel strike and ending at left heel strike.

knee angle data. During the HKC condition, there was an approximate 1:1.2 ratio between the hip and knee angle (1° of hip flexion was 1.2° of knee flexion, R^2=0.97) while during the non-HKC the ratio was approximately 1:1.4 (R^2=0.18). While some coupling occurred, it does not meet the expected ratio

between the two joints as governed by the cylinder sizes, thus the subject was unable to successfully and consistently achieve sufficient foot-floor clearance. The HKC did not improve foot-floor clearance when compared to no HKC. With continuous HKC, the hip was flexed at the end of swing preventing the knee from fully extending. Therefore, the hydraulic circuit needs the functionality of locking and unlocking the hip and knee joints to avoid knee buckling during stance as muscles begin to fatigue.

HKC incorporated into the HNP2

The HNP1 with variable constraint hip mechanism (VCHM) and dual state knee mechanism (DSKM) were modified to incorporate HKC in the prototype HNP2 exoskeleton to provide independent hip locking/unlocking, knee locking/unlocking, hip-hip reciprocal coupling, or hip-knee coupling (**Figure 4**).

Passive Resistance – Bench testing of the HKC mechanism was performed using the Biodex robotic dynamometer (Biodex Medical Systems Inc., Shirley, NY, USA). The hydraulic mechanism was attached to the right upright of the exoskeleton of the HNP2 on the 8020 aluminum stand and affixed to the dynamometer arm. This experiment focused on the hip independent function. The appropriate valves were activated to allow for free movement of the hip while keeping the knee in a fully extended locked position. The dynamometer measured the joint angle, angular velocity, and torque at the hip. Hip joint angles were also recorded using rotary encoders (US Digital, Vancouver, WA, USA) located at the joint centers. Passive resistance was measured at constant angular velocities from 30 to 120°/sec in 30°/sec increments. One calibration trial was performed to measure the passive resistance due to the weight and inertial component of the upright and cylinders without functioning hydraulics at 30°/s. All dynamometer data were collected at 200 Hz. The dynamometer data were filtered online with a 5th –order low-pass digital Butterworth filter with a cutoff frequency of 10 Hz. The dynamometer data were filtered again offline with a 5th – order low-pass digital Butterworth filter with a cutoff frequency of 3 Hz.

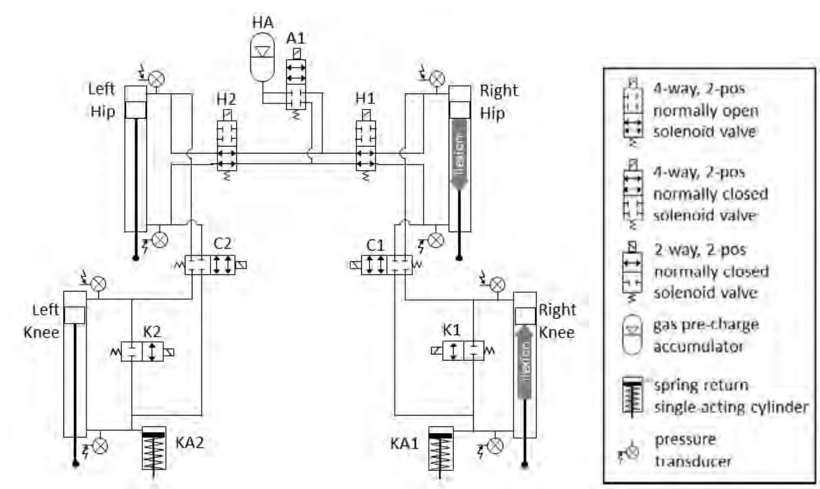
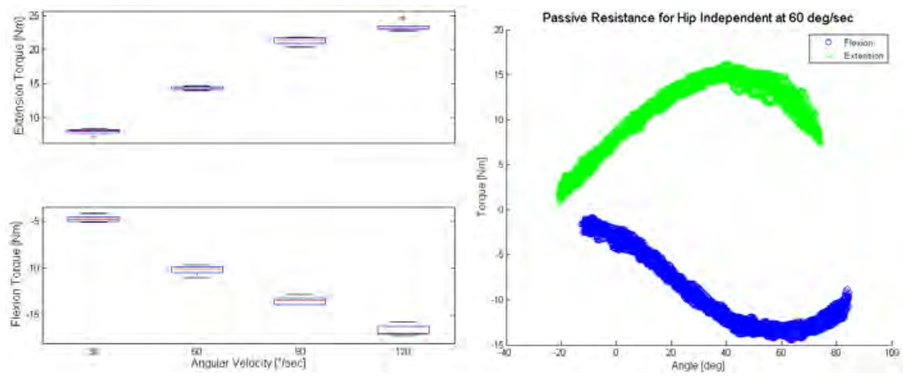


Figure 4. Hip-knee coupling bilateral hydraulic circuit.

Passive resistance is the torque needed to move the system at a specific angular velocity when the hip or knee joints of the HKC mechanism are in a freed/independent or coupled state. The inertial component of the measured dynamometer torque needed to move the mass of the dynamometer arm and HKC mechanism was subtracted from the total measured torque to determine the passive resistance torque due solely to the hydraulics.



a) **b)**

Figure 5. **a)** Passive resistance at 30° of hip flexion as a function of angular velocity and **b)** as a function of hip angle at 60°/s.

The average passive resistance at 30° of flexion when the hip joint is independently flexing (negative) and extending (positive) at increasing angular velocities is shown in **Figure 5a** and as a function of hip angle in **Figure 5b**. The passive resistance generally increases as a function of angular velocity and does not appear to level off. As a function of hip angle, passive resistance at 60°/sec peaked at around 40-50° of hip flexion. A significant reduction in passive resistance was measured when valves were removed from the HKC hydraulic circuit and further when the length of tubing was minimized. Thus, a significant passive resistance is introduced by valves and tubing. Since these components are an integral part of the hydraulic circuit necessary for HKC control they cannot be eliminated. The hip independent testing shows the hydraulics to have high passive resistance, which could make it difficult for individuals with SCI using FNS to achieve sufficient and reliable hip flexion. Earlier work has shown that hip-knee coupling passive resistance is higher than independent joint moments. If this is valid, the passive resistance during hip-knee coupling using this hydraulic system would be even higher than the passive resistance for hip independent, which may be troublesome for achieving sufficient knee flexion via FNS-generated hip flexion.

Hip-Knee Coupled Experiments

The experimental setup and equipment was similar to that used for the hip independent experiment described above. To create hip-knee coupling function, valves H1 and C1 were energized (**Figure 4**). The passive resistance increased with increased angular velocity (**Figure 6a**) and peaked at about 45° of hip flexion (**Figure 6b**). With the hydraulic hip-knee coupling, there was high passive resistance even when

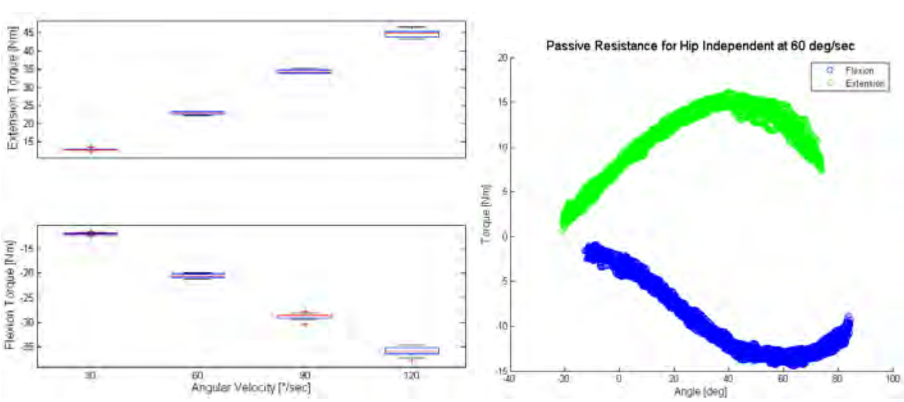


Figure 6. **a)** Passive resistance at 30° of hip flexion as a function of angular velocity and **b)** as a function of hip angle at 60°/s.

the valves were removed. This would make it difficult for individuals with SCI using FNS to achieve good hip flexion and as a result, good knee flexion. Even though the hip-knee coupling ratios (between 0.96 and 1.00) with the newly fabricated uprights (HNP2) were more consistent, the high passive resistance of hydraulic HKC mechanism does not seem functionally relevant or useful to HNP2 with available joint moments generated by the FNS.

As an alternative to hydraulic hip-knee coupling to provide sufficient knee flexion for toe clearance during swing we are pursuing both physiological and mechanical solutions. Physiological solution involves implantation of sartorius and gracilis muscles both providing hip and knee flexion[1]. The mechanical solution involves instrumenting the knee joint with a spring loaded in extension that when released will cause knee and hip flexion at ratios dependent on the inertial properties of the leg and thigh segments, respectively[2]. The knee is extended in mid swing by activation of quadriceps, thus requiring relatively small portion of the available knee extensor strength at a low duty cycle. Initial experiments are underway to test this method. There is also a third option which includes combining the physiological and mechanical solutions.

Task 2 – Refine the design of the currently existing hybrid neuroprosthesis (HNP1) prototype orthosis and hydraulic system to minimize size, weight, enable rapid fitting, and provide easy donning and doffing in the field.

Redesign of Variable Constraint Hip Mechanism

To minimize the size and weight of the hydraulic circuit, the VCHM and DSKM of the HNP1 were redesigned, constructed, and incorporated into the HNP2 to coordinate motion of the right hip with the left hip, and to be able to lock and unlock the knees as needed during gait. The hydraulic circuit states are: hip independently free or locked, hip-hip reciprocally coupled, and knees independently free or locked. In the VCHM two 2-way valves were replaced with one 4-way, 2-position valve to reduce the number of valves needed to create the same functions (reducing the number of valves from six to three), as shown in **Figure 7**. In the DSKM the 9/16” bore cylinder was replaced with a 7/8” bore cylinder to satisfy the knee stand-to-sit torque requirements. Once assembled and attached to new uprights, the hydraulic circuit was bench tested for passive resistance of the right hip independent motion, hip-hip reciprocal coupling motion, and right knee independent motion.

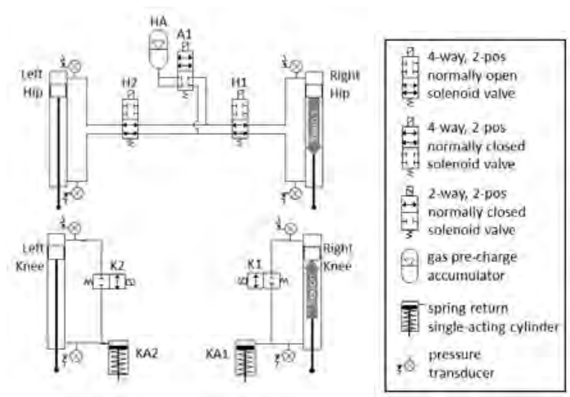


Figure 7. HNP2 hydraulic circuit schematic.

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[1] Kobetic R, Marsolais EB, Miller PC. Function and strength of electrically stimulated hip flexor muscles in paraplegia. *IEEE Trans Rehab Eng,* 2(1):11-17, 1994.

[2] Huq MS, Tokhi OM, Genetic algorithms based approach for designing spring brake orthosis – Part I: Spring parameters. *Applied Bionics and Biomechanics*, 9:303-316, 2012.

The hydraulic circuit schematic shown in **Figure 7** and realization shown in **Figure 8**, using the components listed in **Table 1** was utilized for the bench testing. After the hydraulic circuit was fabricated and primed with hydraulic fluid (i.e. replaced air in the circuit with hydraulic fluid), bench testing was performed to (1) analyze the passive resistance due to the hydraulics and (2) determine the locking torque and compliance at the hip and knee joints with their respective systems. The system was pressurized (i.e. precharged) to approximately 70 psi to reduce the effect of residual air bubbles in the system after priming.

Table 1. Hydraulic Components for VCHM and DSKM Mechanisms.

	Hip and knee cylinders	**hip valves**		**knee valve**	**hip accumulator**	**knee accumulator**
manufacturer	Clippard Minimatic	Hydraforce	Hydraforce	Allenair	Hydac	Clippard Minimatic
type	double acting	4-way, 2-pos Normally Closed	4-way, 2-pos Normally Open	2-way, 2-pos Normally Closed	gas pre-charge (58 psi) diaphragm, 0.075 L	single acting spring return
bore	7/8”	-	-	-	-	3/4”
port	1/8” NPT	SAE 6	SAE 6	1/8” NPT	SAE 6	1/8” NPT
stroke	3”	-	-	-	-	1”
rod diameter	0.25”	-	-	-	-	0.25”
voltage	-	12 VDC	12 VDC	12 VDC	-	-
power consumption	-	14.4 W	14.4 W	7 W	-	-
max operating pressure	2000 psi	3000 psi	3000 psi	46 ± 7 psi (cracking pressure)	3600 psi	250 psi
spring force	-	-	-	-	-	3 lbs installed 6 lbs compressed

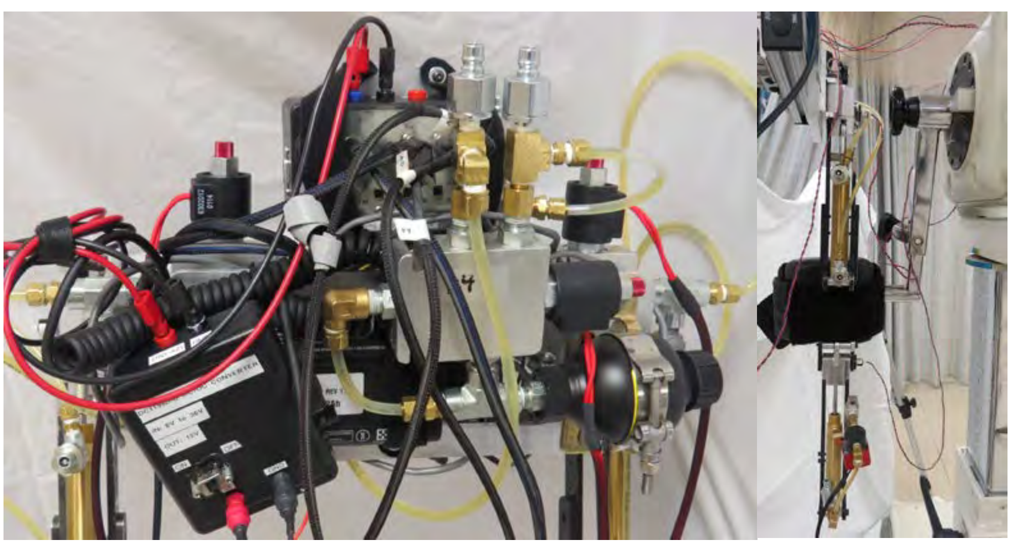


Figure 8. VCHM2 and DSKM2 hydraulic circuit realizations with electronics attached.

Bench testing of the VCHM2 and DSKM2 were performed using the Biodex® robotic dynamometer. The hydraulic mechanism was attached to the right side upright of the exoskeleton of the HNP2 on the 8020 aluminum stand and affixed to the dynamometer arm (**Figure 9**). The first experiment focused on the hip joint during hip independent and left (L) hip-right (R) hip reciprocal coupled movement. Valves A1 and H2 were energized to create hip independent function. No valves were energized to create L hip-R hip reciprocal coupling, since that is the default unpowered state of the VCHM. Valve H1 was energized to close the valve and lock the right hip. For the knee experiment, valve K1 was energized to unlock/free the knee but it was de-energized to lock the knee during the locking torque and compliance testing. Hip and knee joint angles were recorded using rotary encoders (US Digital, Vancouver, WA, USA) located at the joint centers. The experiment was performed with repetitive trials which consisted of the dynamometer arm moving at least ten repetitions in succession without stopping in between full joint flexion and extension range of motion. The dynamometer measured the joint angle, angular velocity, and torque of the joint aligned at its center of rotation (i.e. hip or knee joint). The dynamometer arm was set in passive mode and passive resistance was measured at constant angular velocities, starting at 30°/s and up to 120°/s in 30°/s increments. Calibration trials were performed for the hip independent and knee independent function to measure the passive resistance due to the weight and inertial component of the upright and cylinders without functioning hydraulics at 30°/s. A static calibration trial was performed to determine an approximate calibration passive resistance for the hip-hip reciprocal function, in order to take into account the weight of the opposite (left) side. The calibration passive resistance data was subtracted from the trials with functioning hydraulics to determine only the passive resistance due to the hydraulic system. Dynamometer data were collected at 200 Hz. The dynamometer data were filtered online with a 5th –order low-pass digital Butterworth filter with a cutoff frequency of 10 Hz. The dynamometer data were filtered again offline with a 5th – order low-pass digital Butterworth filter with a cutoff frequency of 3 Hz, and the encoder data were filtered offline with a moving average filter (50ms).

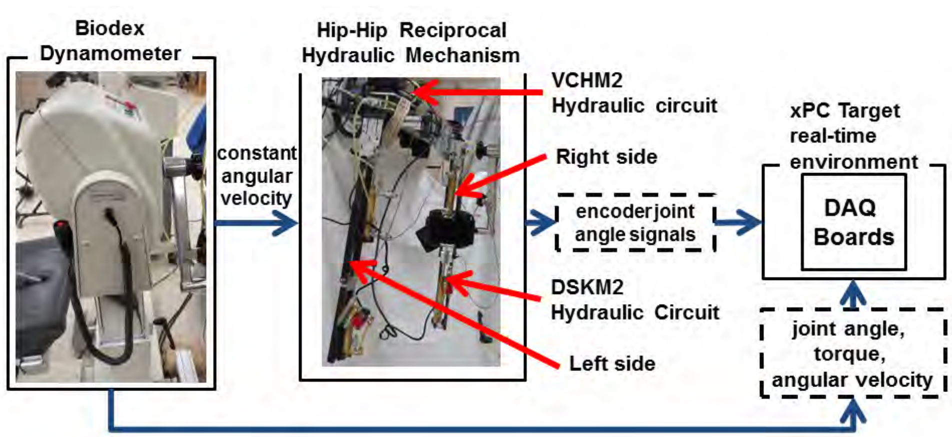


Figure 9. Experimental setup with Biodex dynamometer.

Hip Passive Resistance – is the torque needed to move the system at a specific angular velocity when the hip joint is either freed or reciprocally coupled to the contralateral hip. The inertial component of

the measured dynamometer torque needed to move the mass of the dynamometer arm and VCHM was subtracted from the total measured torque to determine the passive resistance torque due solely to the hydraulics.

The average passive resistance measurements at 30° of flexion when the hip joint was flexing (negative) and extending (positive) at increasing angular velocities are shown in **Figure 10**. Maximum angular velocity during able-bodied gait occurs near a knee flexion angle of 30°. Because passive resistance increases with angular velocity, the largest amount of passive resistance should occur at the knee angle of 30°. In general, the passive resistance will increase as the angular velocity increases. Linear trend lines could be fit to the data seen in **Figure 10** to quantify the linear relationship, as seen in **Table 2**. The

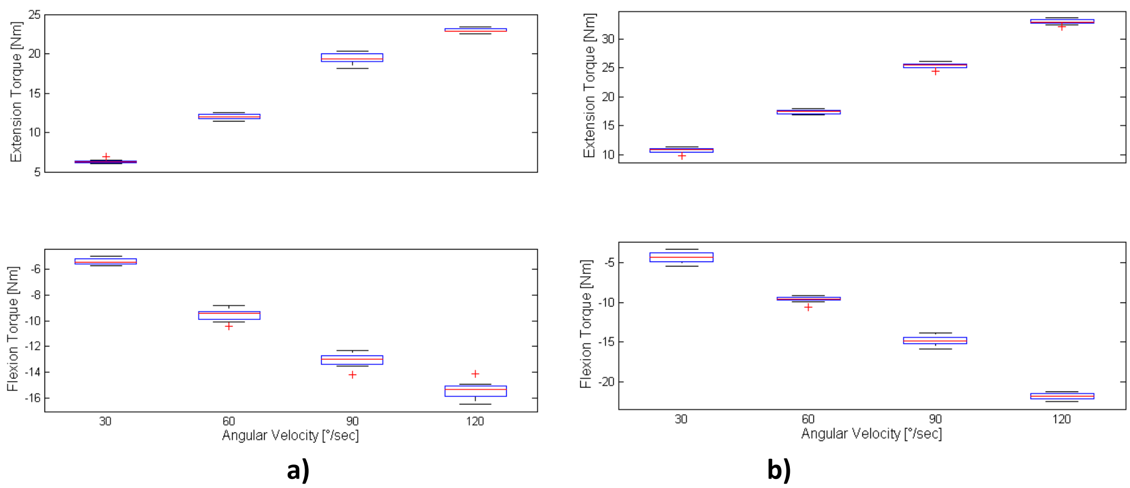


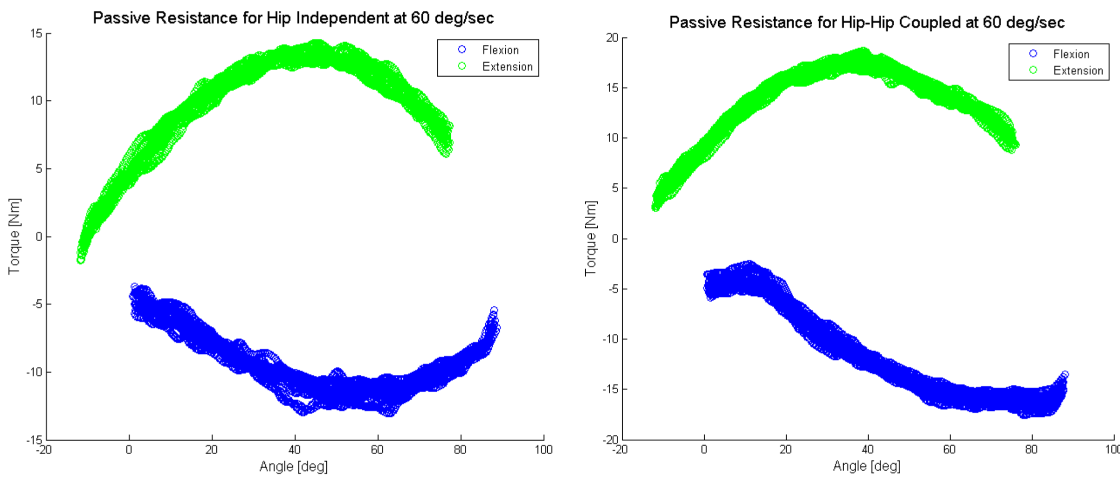
Figure 10. Passive resistance at 30° of flexion for the VCHM2 when the hip is flexing (negative) and extending (positive) for **a)** hip independent and **b)** L hip-R hip reciprocally coupled.

passive resistance generally increases as a function of angular velocity and does not appear to level off at any particular angular velocity. Negative torque in **Figure 10a&b** indicates resistance to flexion, and positive torque indicates resistance to extension.

Table 2. Passive resistance as a function of angular velocity at hip joint.

Movement	Hip Independent	Hip-Hip Reciprocally Coupled
Flexion	$y = 0.1108x + 2.5459$	$y = 0.1928x - 1.8314$
Extension	$y = 0.1910x + 0.8362$	$y = 0.2493x + 2.9554$

In addition, the passive resistance was determined as a function of hip angle over the specific constant angular velocity of that trial. The passive resistance at 60°/s is shown in **Figure 11** for hip independent and hip-hip reciprocally coupled. For 60°/s, the passive resistance increases to a peak torque around 40-50° of hip flexion.



a) **b)**

Figure 11. Passive resistance as hip angle increases during constant angular velocity of 60°/s for **a)** hip independent and **b)** L hip-R hip reciprocally coupled.

Hip Locking Torque and Compliance

The VCHM2 needs to be able to resist at least 35Nm of applied torque[3] to support a subject with SCI during gait. Measurements were performed by using the dynamometer to apply a flexion torque about the hip joint while the hip joint was locked against flexion. Compliance was defined as a change in angle with applied torque to the hip mechanism. The applied torque was manually increased to at least 60Nm in each trial.

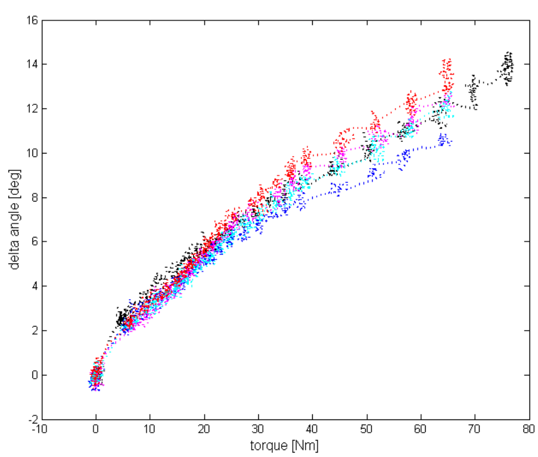


Figure 12. Locking compliance of the VCHM2 relative to applied torque.

The VCHM2, with hip cylinder locked, was able to withstand at least 60Nm of applied flexion torque, which suggests that it should support a person with paraplegia against hip flexion when locked. The compliance increased as the applied torque was increased as shown in (**Figure 12**). Approximately 8° of compliance occurs at 35Nm, to an approximate maximum of 10-12° of compliance at 60 Nm.

Hip Reciprocal Coupling Ratio

The hydraulic circuit tested has the function of coordinating the right hip with the left hip i.e. for every degree of right hip flexion there should be an equal left hip extension. The relationship between the right and left hip angles during early swing was determined using the rotary encoders, namely the hip-hip reciprocal coupling ratio. The slope of the hip-hip angle plot during constant angular velocity was

[3] Perry J. Gait Analysis: Normal and Pathological Function. Thorofare, NJ: SLACK Incorporated, pp. 92, 94, 1992.

used to determine the ratio of the joints during the coupling function as listed in **Table 3**. Coupling ratios of the new VCHM2 at all angular velocities were within 3 to 4% of the 1:1 design criteria as expected.

Table 3. Slopes of linear trend lines fit to right and left hip angles during constant angular velocities.

30°/s	60°/s	90°/s	120°/s
1.027 ± 0.002	1.036 ± 0.003	1.036 ± 0.004	1.034 ± 0.003

Dual State Knee Mechanism

Knee Passive Resistance – The inertial component of the measured dynamometer torque needed to move the mass of the dynamometer arm and DSKM2 was subtracted from the total measured torque to determine the passive resistance torque due solely to the hydraulics.

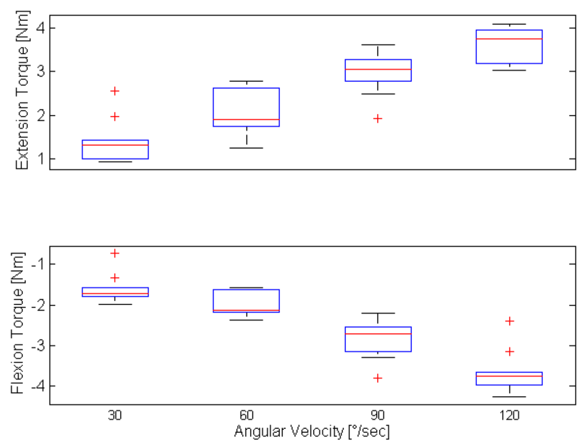


Figure 13. Passive resistance at 30° of flexion for the DSKM2 for knee independent.

The average passive resistance measurements at 30° while flexing (negative) and extending (positive) the kneeat increasing angular velocities are shown in **Figure 13**. As mentioned previously, able-bodied gait kinematics show that the maximum angular velocity during gait occurs near a knee flexion angle of 30°. Because passive resistance is proportional to angular velocity, the largest amount of passive resistance should occur at the knee angle of 30°. Linear trend lines could be fit to the data seen in **Figure 13** to quantify the linear relationship, as seen in **Table 4**.

Table 4. Passive resistance as a function of angular velocity at the knee joint

Movement	Knee Independent
Flexion	$y = 0.0236x + 0.7706$
Extension	$y = 0.0251x + 0.6286$

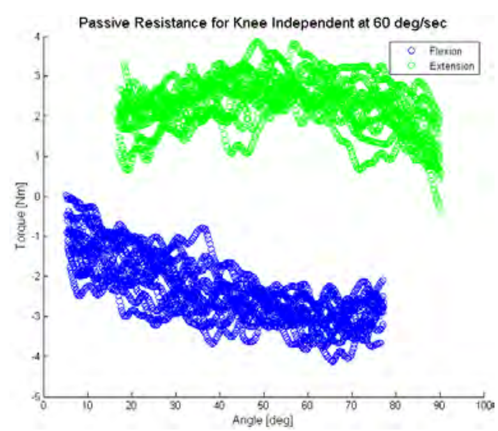


Figure 14. Passive resistance of the DSKM2 moving at constant angular velocity of 60°/s.

The passive resistance generally increases as a function of angular velocity and does not appear to level off at any particular angular velocity. Negative torque indicates resistance to flexion, and positive torque indicates resistance to extension.

In addition, the passive resistance was determined as a function of knee angle over the specific constant angular velocity of that trial. The passive resistance at 60°/s is shown in **Figure 14**.

Knee Locking Torque and Compliance

The DSKM2 needs to be able to resist at least 50Nm of applied static torque[4] at or near full knee extension, which should be able to support a subject with SCI during stance phase of gait. This experiment was performed by using the robotic dynamometer to apply a flexion torque about the knee joint while it was locked against flexion. The applied torque was manually increased to a maximum of 70Nm in each trial (**Figure 15**).

The DSKM2, with knee cylinder locked, was able to withstand at least 70Nm of applied flexion torque, which suggests that it should support a person with paraplegia against collapse. The compliance is the amount of joint angle change that occurs when the system is locked against flexion and the dynamometer arm applies a flexion torque. The compliance increases as the applied torque is increased. Approximately 4° of compliance occurs at 70 Nm.

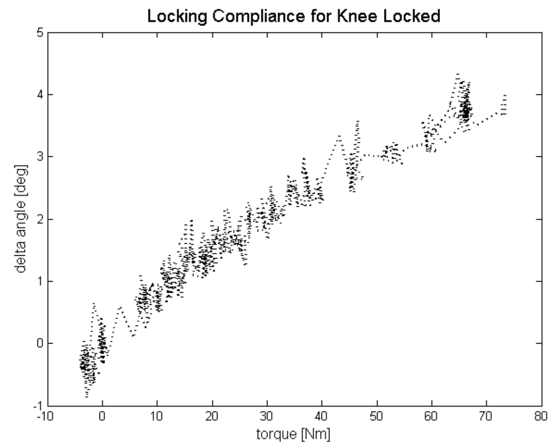


Figure 15. Compliance of the locked DSKM2 as a function of applied torque.

Discussion of Hip and Knee Mechanisms

The passive resistance at the VCHM2 hip joint is greater than previous work done with the VCHM that had median torques up to but not exceeding 6Nm[5]. FNS is capable of generating about 60Nm of hip flexion torque and 70Nm of hip extension torque[6]. Thus, approximately 18% of the hip flexion torque and approximately 22% of the hip extension torque generated by FNS will be needed to overcome the passive resistance during hip independent motion for this modified VCHM2 circuit. About 21% of the hip flexion torque and approximately 31% of the hip extension torque generated by FNS will be needed to overcome the passive resistance during left hip-right hip reciprocal coupling for the VCHM2 circuit. The passive resistance for the VCHM2 is higher than the VCHM1 (7% of hip flexion torque and 10% of hip extension torque). Potential contributions for the increased passive resistance may include the combination of tubing/hose length and valves.

The locked hip mechanism needs to be able to resist 35Nm of applied torque in order to support a subject with SCI during walking. The VCHM2 and uprights used were able to withstand at least 60Nm of applied flexion torque, which suggests that the hip mechanism would be able to support against hip flexion when locked. In addition, any locking compliance would be undesirable and kept to a minimum, since the compliance would reduce the effectiveness of support against forward trunk lean. The

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[4] Perry J. Gait Analysis: Normal and Pathological Function. Thorofare, NJ: SLACK Incorporated, pp. 92, 94, 1992.

[5] To CS. Closed-loop control and variable constraint mechanisms of a hybrid neuroprosthesis to restore gait after spinal cord injury. PhD Dissertation, Case Western Reserve University, 2010.

[6] Kobetic R, Marsolais EB. Synthesis of paraplegic gait with multichannel functional neuromuscular stimulation. *IEEE Trans Rehab Eng.* 3(2): 66-79, 1994.

compliance of the locked hip mechanism at 35Nm is about 7-8° and increases to about 10-12° of flexion at 60Nm. The system allows for a similar amount of trunk tilt as seen in reciprocating gait orthoses[7]. The VCHM2 and uprights will allow for a few degrees of flexion when the hips are locked but still support the user from an excessive forward lean.

The ratio of the hip-hip reciprocal coupling, with respect to joint angles, is approximately 1:1. About one degree of right hip flexion will result in one degree of left hip extension. This cannot be equated with mechanical efficiency because it does not relate flexion torque to extension torque. One of the main purposes for the VCHM2 is not to transfer torque from one hip to the other, but to restrict the hips from simultaneously moving in the same direction to avoid the tendency for bilateral hip flexion and forward trunk lean.

The passive resistance at the DKSM2 knee joint is approximately the same as, though slightly higher than, the previous work done with the DSKM that had median torques up to 2Nm (13% of knee flexion moment) in flexion and 1Nm (1% of knee extension moment) in extension. FNS is capable of generating about 15Nm of knee flexion moment and 80Nm of knee extension moment[8]. For knee flexion with the DSKM2, about 17% of the knee flexion moment generated by FNS will be needed to overcome the passive resistance in flexion. Approximately 3% of the knee extension moment generated by FNS will be needed to overcome the passive resistance in extension with the DSKM2. The passive resistances are slightly higher than the previous DSKM and may be attributed to the larger 7/8" bore cylinder being used. The larger cylinder has larger stiction and viscous effects that increase the passive resistance at the knee, which are minimal and tolerable in the system. However, the larger cylinder does mean the weight of the hydraulic mechanism is also increased, in addition to the passive resistance. Users should be able to extend the knee with ease, especially if stimulating the quadriceps muscle for knee extension. However, knee flexion may be more challenging, since the potential knee flexion moment generated by FNS is relatively small. Because of this, some type of knee flexion assist might be beneficial to help counter the added weight and passive resistance that is created by the DSKM2 with a larger cylinder.

The locked knee mechanism needs to be able to withstand about 50Nm of torque during loading response of stance phase of gait. The DSKM on the new uprights was able to support up to 70Nm with a compliance of 4° of flexion. This is minimal compliance in the locked knee joint when loaded.

The bench testing showed hydraulic hip-hip coupling with the 4-way valves ov the VCHM2 has higher passive resistance than the VCHM1 using Allenair valves, which could potentially make it difficult for volunteers with SCI using FNS to achieve good hip flexion. The passive resistance for the DSKM2 using a 7/8" bore cylinder is reasonable and comparable to the DSKM1 using a 9/16" bore cylinder. The number of valves decreased in the VCHM2 and reduced the assembly space on the back of the corset. The DSKM2 packaging is about the same as the DSKM1 (just with a larger cylinder). The locking compliance

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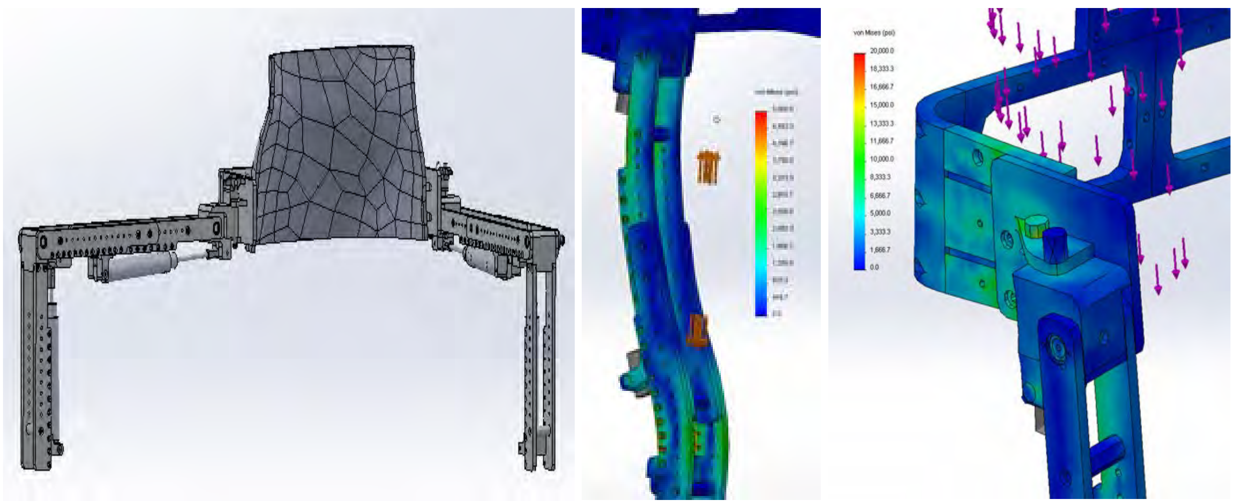
[7] Marsolais EB, Kobetic R, Polando G, Ferguson K, Tashman S, Gaudio R, Nandurkar S, Lehneis HR. The Case Western Reserve University hybrid gait orthosis. *J Spinal Cord Med*., 23(2): 100-108, 2000.

[8] Kobetic R, Marsolais EB. Synthesis of paraplegic gait with multichannel functional neuromuscular stimulation. *IEEE Trans Rehab Eng.* 3(2): 66-79, 1994.

and locking torque capabilities of the VCHM2 and DSKM2 are both comparable, if not better, than the previous versions. The DSKM2 is definitely comparable and satisfies the needs for a locking and unlocking knee mechanism. The VCHM2 locking compliance and torque capabilities are good, while the passive resistance is starting off higher than desired but not as high as previous experiments with the hip-knee coupled mechanism.

Design of Exoskeleton

The exoskeleton of the HNP2 has been redesigned to include thigh and shank adjustable overlapping double uprights with interconnecting members and coplanar cylinders mounted between to fit users of wide range of statures (5th percentile female to 95th percentile male). The uprights with lateral projection of 5.8cm have swivel hip joints for abduction and ease of donning and doffing (**Figure 16**). The hip attachment to the corset mounting frame is by means of a dovetail joint to allow anterior-posterior adjustment to align the joint center with the user.



a) b) c)

Figure 16. SolidWorks drawing **a)** shows the uprights design with lockable swivel hip joints for easy donning and doffing while sitting in a chair. FEA of upright **b**) and corset frame with hip joint **c**) under loading conditions showing no significant stress concentrations that would compromise safety.

A Finite Element Analysis (FEA) was performed on the uprights and corset frame to ensure the safety of the supporting structure made from 6061-T6 Aluminum alloy during loading. The upright was loaded with a maximum load of 330kg applied at the cylinder attachment points as shown in **Figure 16b**. The maximum upright stresses were less than 5ksi which meets > 2.5 safety factor against failure. Similarly, the corset frame was loaded with 90kg while supported on a single upright. The stresses shown in **Figure 16c** produced by the loading were significantly lower that the yielding stress of 40ksi for 6061-T6 Aluminum alloy. Thus, the designed was verified to be structurally sound against failure.

The new prototype exoskeleton was manufactured, assembled and instrumented with sensors for feedback control. All movements were smooth and unhindered except for passive resistance of hydraulic mechanisms. A pin lock hip abduction joints provide a positive lock and engagement to

prevent accidental release, but they can also be removed for ease of donning/doffing with uprights abducted. Attachments for the custom fitted orthotic components (ankle foot orthoses (AFOs) and thoracic corset) to the exoskeleton were designed and implemented (**Figure 17**). These custom fitted orthotic components allow for efficient motion transfer from the user to the exoskeleton and prevent pressure concentrations. Exoskeleton fitting and adjustment (adjusting the length of the leg segments and posterior/anterior location of the hip joint) process tested on two able-bodied volunteers was relatively quick and easy with the use of commonly available hand tools. Attachments for Velcro thigh cuffs were designed, 3D printed, and provided a close coupling between the exoskeleton and the user.

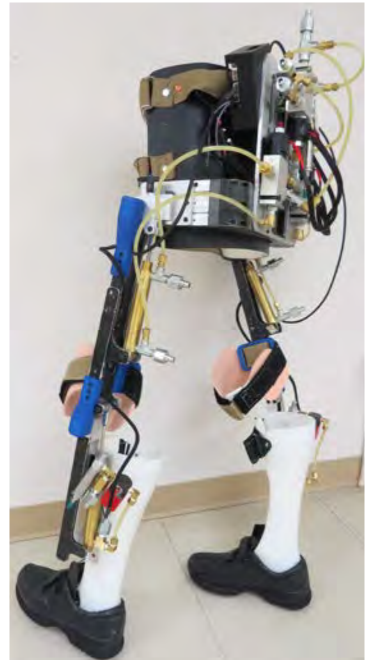


Figure 17. Assembled exoskeleton for HNP2.

More significantly, the back mounted hydraulics were redesigned to decrease overall weight and posterior projection, thus, minimizing inertial moment to improve comfort and safety of the device. This redesign has reduced the weight/moment by relocating the relatively heavy hydraulic valves closer to the frame, as well as replacing the previous cast iron, nitrogen pre-charged accumulator with a lighter aluminum, spring loaded unit of smaller capacity. Despite this change, no loss of function is anticipated, in contrary, with the shorter lengths of tubing, a decrease in passive resistance should be realized. The total weight of the exoskeleton including hydraulics, electronics and power supply is 18.1kg as compared to 22.2kg for exoskeleton of the HNP1; a saving of 18.5%.

Task 3 – Design, develop and implement a new control system to automatically coordinate electrical stimulation with hydraulic exoskeleton using a mobile computing platform.

Hardware and Software Development

The HNP2 mobile control system hardware includes sensors, signal conditioning board, stimulation board, embedded control board, and power supply (**Figure 18**). The signal conditioning board receives

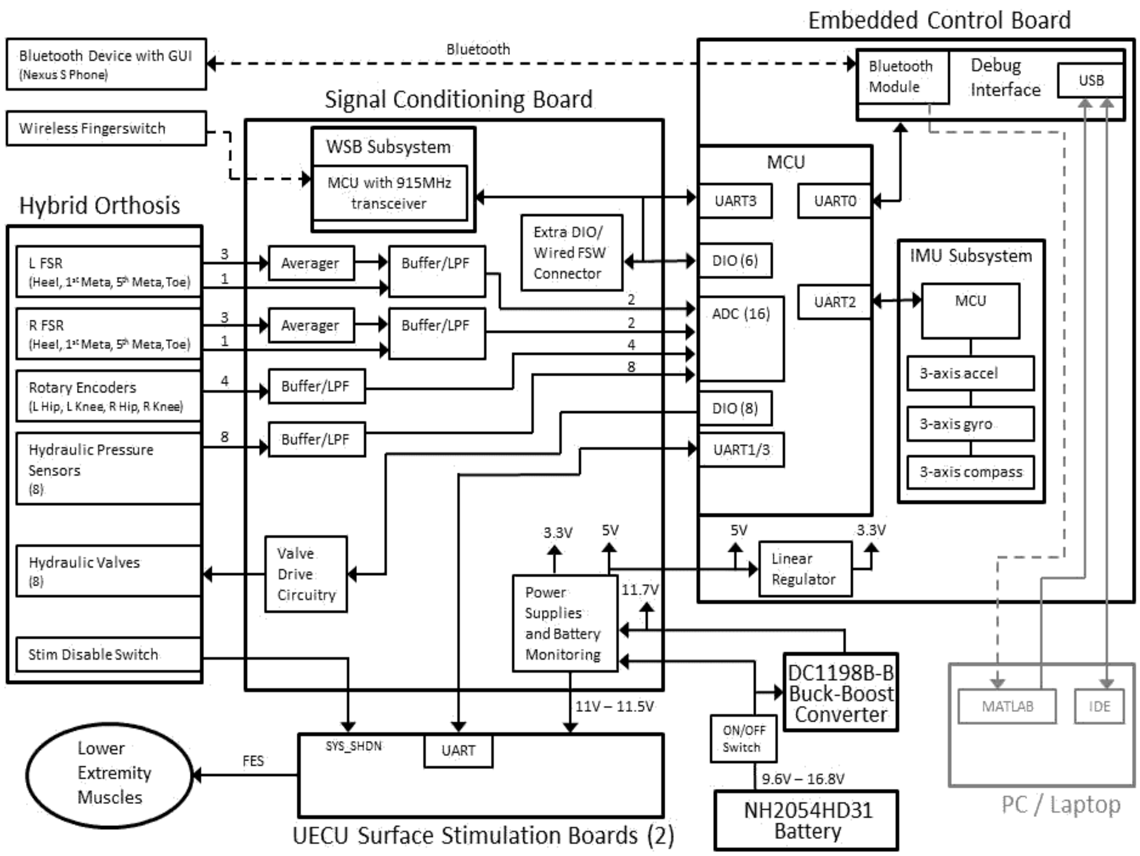


Figure 18. HNP2 control hardware block diagram.

and conditions sensor signals from left and right foot sensing resistors (FSRs) placed between the AFOs and shoes, signals from encoders at hips and knees, and signals from hydraulic pressure sensors. In addition, the signal conditioning board provides control/drive signals for hydraulic valves.

The embedded control board (ECB) is the brain of the HNP2. It interfaces with the signal conditioning board and stimulation boards. The embedded control board samples the analog sensor signals and generates the digital valve control signals. It can communicate with a PC/laptop either wirelessly or through a USB port for software development. In addition, ECB communicates wirelessly with an Android-based smart phone or a hand switch used as a user interface for selecting and activating functional tasks (i.e. stand-up, sit down, walk, climb stairs, etc.).

A graphical user interface (GUI) on the smart phone has three windows (**Figure 19**):

a) **Main Window:** to monitor battery states and select walking mode.
b) **Settings Window:** system/sensor calibration.
c) **Expert Window:** to monitor sensor states and stimulation pattern state.

a) **b)** **c)**

Figure 19. Smart phone GUI interface a) main window, b) setting window, and c) expert window.

The embedded control board has a microprocessor control unit which runs the finite state controller, and based on sensor inputs, user command, and an onboard inertial measurement unit (IMU), provides control signals to activate and deactivate the solenoid hydraulic valves to either lock or free the knee joints and lock, free or couple the hip joints. The ECB also sends control signals to the stimulation board for muscle activation and synchronizes it with activities of the exoskeletal joints based on gait event detector.

The signal conditioning board, embedded control board and stimulation boards were fabricated and are stacked in the enclosure for ease of connections (**Figure 20**). The circuitry has been tested and is functioning as intended. It can be controlled remotely by a smart phone and stream data wirelessly to a PC/laptop.

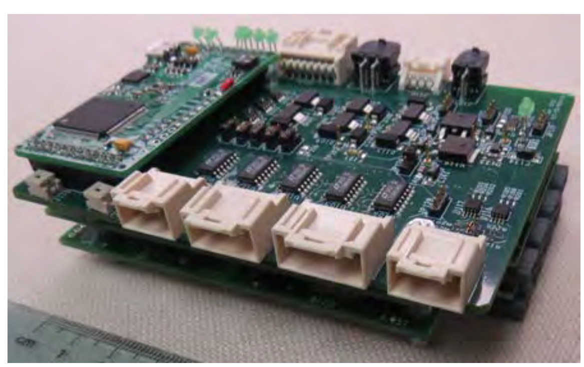
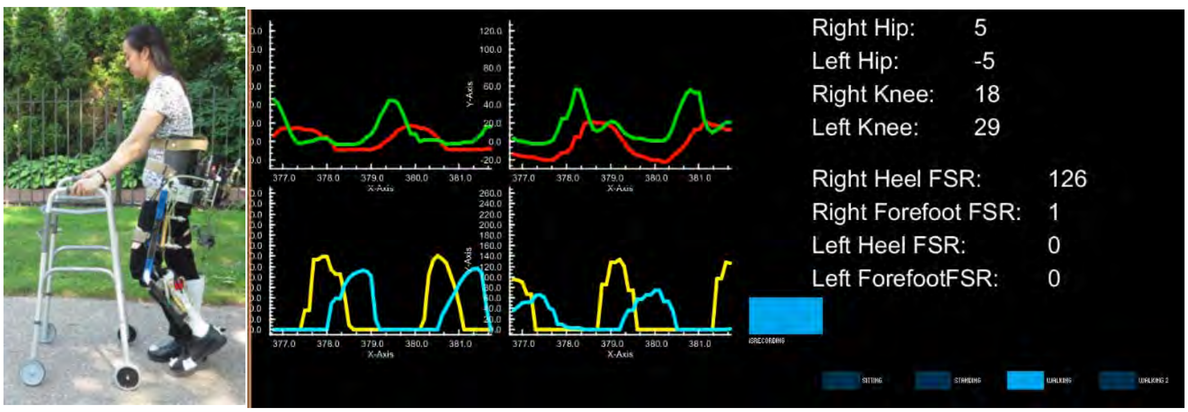


Figure 20. Controller hardware including SCB, ECB (top left), and 2 stimulation boards.

Preliminary Testing of Untethered HNP2

A GUI was developed on PC/laptop to communicate wirelessly with a finite state controller running onboard HNP2. A gait event detector using FSRs as inputs to the finite state controller running on embedded controller board determined phases of gait in an able-body subject to reciprocally couple the hips and free the knees during swing and lock them during stance. For example, the subject indicated intent to make a step by shifting weight to the contralateral leg, thus unloading the ipsilateral FSRs causing the knee to unlock for swing and lock for stance phase at heel strike in preparation for next step. Sensor signals from hip and knee joints and FSRs are streamed wirelessly to PC/laptop for real time display on a GUI and post-processing (**Figure 21**).



a) **b)**

Figure 21. a) Able-bodied subject walking with untethered HNP2, and **b)** wirelessly streamed real time hip and knee angle and FSR data from embedded control board displayed on a remote PC.

KEY RESEARCH ACCOMPLISHMENTS:

1. Designed and constructed hydraulic hip-knee coupling mechanism and determined its passive resistance and coupling ratio.
2. Designed, constructed and evaluated a new adjustable exoskeleton frame for attachment of customized corset and ankle foot orthoses and ease of donning and doffing. This included left and right leg uprights, metal torso frame, hydraulic cylinder mountings, and hydraulic and electronic circuitry mounting frame.
3. Designed and assembled a new variable constrained hip mechanism (VCHM2) and dual state knee mechanism (DSKM2).
4. Determined passive resistance, compliance and locking torque for VCHM2 and DSKM2.
5. Assembled a complete exoskeleton with hydraulic mechanisms at hips and knees.
6. Reduced total weight of the system by 18% from HNP1.
7. Instrumented exoskeleton with sensors to measure joint angles and foot pressure and made provisions to measure hydraulic pressure.
8. Designed and fabricated signal conditioning board, embedded control board, and power supply.
9. Designed software to run a simple onboard finite state controller and stream real time data wirelessly to a PC/laptop for display and processing.

10. Designed a smart phone mobile app and wireless hand switch for user interface for function selection and HNP2 state monitoring.
11. Established untethered operation of HNP2 in an able-bodied subject with onboard microprocessor running finite state controller.

REPORTABLE OUTCOMES:

- **manuscripts, abstracts, presentations;**

Poster presentations:

Presented poster titled "Coordinating Hip and Knee Joints with A Hybrid Neuroprosthesis" at the 36th Annual International Conference of the Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society (EMBC'14) in Chicago, IL.

Presented poster titled "Design of an Orthotic Mechanism to Control Stand-to-Sit Maneuver for Individuals with Paraplegia" at Research ShowCASE, Case Western Reserve University, Cleveland, OH (2015.04.17).

Oral presentation titled "Design of Orthotic Mechanisms to Control Stand-to-Sit Maneuver for Individuals with Paraplegia" at World Congress IUPESM (WC2015) in Toronto, Canada.

- **licenses applied for and/or issued;**

  US Patent Application Publication No.: US2014/0358053 A1,
  Pub Date: Dec 4, 2014.
  POWER ASSISTED ORTHOSIS WITH HIP-KNEE SYNERGY

- **degrees obtained that are supported by this award;**
  - ***Opportunity for students to get involved in research***
    - Sarah Chang, B.S., graduate student, PhD., candidate in Biomedical Engineering
    - Mark Nandor, M.S., graduate student Ph.D., candidate in Mechanical Engineering
    - Lu Li, B.S., graduate student, M.S. candidate in Mechanical Engineering
    - Kiley Armstrong, undergraduate Mechanical and Biomedical Engineering student
    - Maria Lesieutre, undergraduate student majoring in Mechanical with minor in Biomedical Engineering.
    - Theodore Frohlich, undergraduate student majoring in Biomedical Engineering

- **funding applied for based on work supported by this award;**
  - Maria Lesieutre, applied and received SOURCE funding from CWRU to do summer research project on control of knee stiffness and damping for the stand-to-sit maneuver with HNP.
  - Sarah Chang, applied and received a training grant #: 5T32AR007505-28 from a Training Program in Musculoskeletal Research of the NIH. To pursue her graduate studies.
- **employment or research opportunities applied for and/or received based on experience/training supported by this award**

Personnel	Role	Percent Effort
Ronald J. Triolo	Principal Investigator	10%
Musa L. Audu	Co-Investigator	10%
Roger Quinn	Co-Investigator	10%
Rudi Kobetic	Senior Engineer	10%
Mark Nandor	Mechanical Engineer	40%
John Schnellenberger	Electrical/Electronics Engineer	30%
Kevin Foglyano	Biomedical Engineer	10%
Lu Li	Computer/Software Engineer	50%
Dennis Johnson	Electronics Technician	10%

CONCLUSION:

A considerable effort has been expended and significant progress has been made in all three tasks.

The hydraulic hip-knee coupling mechanism was designed, fabricated and evaluated. A significant passive resistance introduced by valves and hosing made this mechanism unsuitable for inclusion in the HNP2. Alternative physiological and mechanical approaches to improve foot clearance during swing are being investigated.

The VCHM2 and DSKM2 were redesigned, assembled and tested. Results show comparable passive resistance to HNP1 with advantages of reduced weight. The exoskeleton structure was designed fabricated and tested. It provides for attachment of custom fitted corset and ankle foot orthoses with adjustable uprights for fitting and abduction hip joint for ease of donning and duffing. The exoskeleton was completely assembled with new VCHM2 and DSKM2, angle and foot pressure sensors, and custom fitted orthotics at the total weight reduction of 18% as compared to HNP1.

A mobile computing platform based on Arduino hardware (embedded control board) was designed and fabricated to interface with existing stimulation control hardware. A signal conditioning board was designed fabricated and tested. Software for a finite state controller running on onboard microprocessor controlling exoskeletal hip and knee constraints based on sensor data input was written and tested during able body walking. Sensor data was streamed wirelessly to a PC/laptop for real time viewing and post processing.

These accomplishments resulted in the first demonstration of untethered operation of the refined hybrid neuroprosthesis (HNP2) outside of the laboratory.

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2. To CS, Kobetic R, Bulea TC, Audu ML, Schnellenberger JR, Pinault G, Triolo RJ (2011). Stance control knee mechanism for lower-limb support in hybrid neuroprosthesis. *Journal of Rehabilitation Research & Development*, 48(7):839-850. DOI:10.1682/JRRD.2010.07.0135.
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